Industry Experience with Electronic Submissions
-CDER perspectives

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Overview

Electronic submissions -FDA perspectives

- **Transition from paper to electronic**
- **Industry response to guidance**
- **Reviewer response**
- **Internal issues being addressed**
- **External issues being addressed**
- **Selling points for electronic submissions**

Electronic submissions - FDA perspective -Congressional mandate for change from paper to electronic

Difficulty with change

- Individual choice change to standard
- Reviewer change methods of review
- Reviewer education and training
- Processing inefficiency with mixed paper and electronic environment

Electronic submissions - FDA perspective - Transition from paper to electronic

Difficulty with transition

- Review inefficiency with infrequent electronic submission
- Review inefficiency with mixed paper and electronic submissions
- Processing costs increased with mixed paper and electronic environment

Electronic submissions - FDA perspective - Benefits of electronic environment

Improvement in:

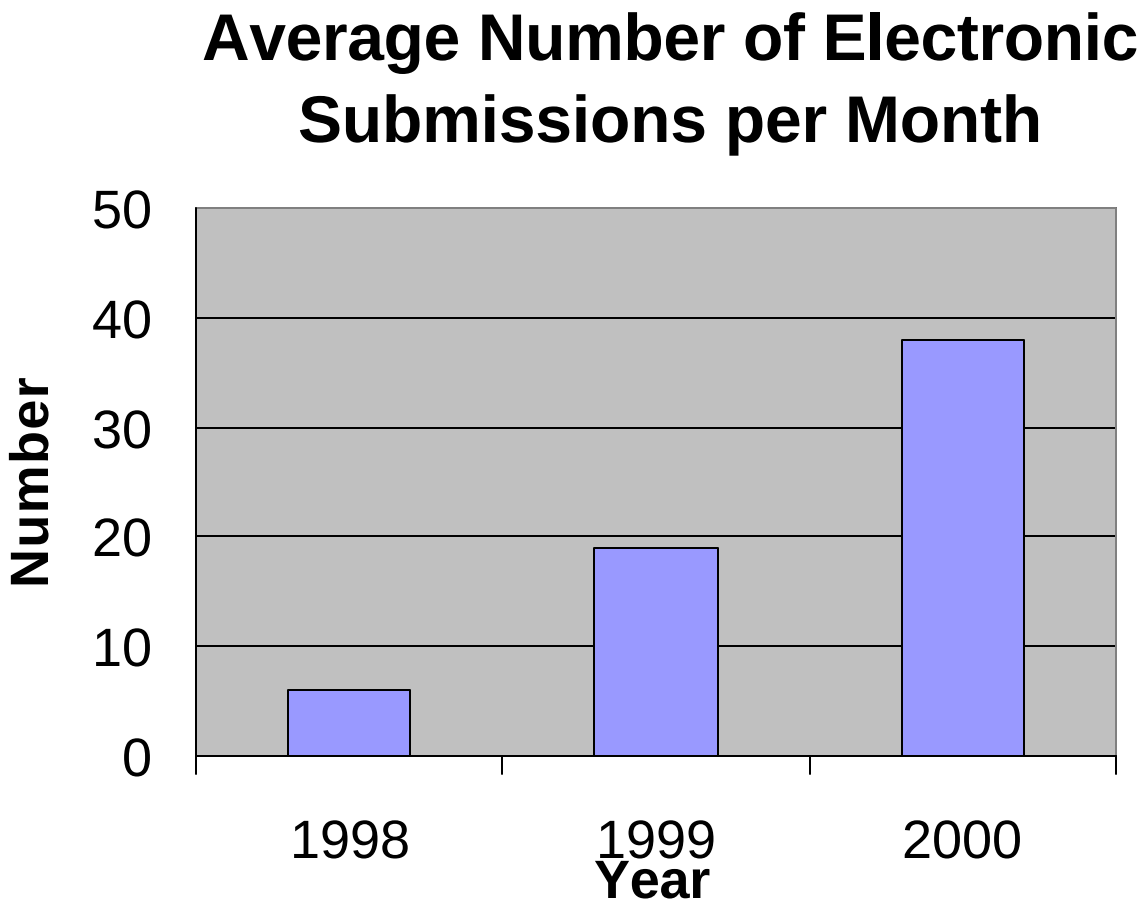
- **Processing efficiency**
- **Submission quality**
- **Review efficiency**
- **Review management**

Electronic submissions - FDA perspective - Road to electronic environment

Transition to electronic submissions

- Voluntary electronic submissions
- Reviewer education and training
- Internal documents electronic
- Regulation changes to require electronic submissions

Electronic submissions - FDA perspective - Voluntary electronic NDAs



Electronic submissions - FDA perspective - Voluntary electronic NDAs

Increase in the number of applicants sending in electronic submissions

- Number doubled between 1998 and 1999
- Close to doubling between 1999 and 2000 based on the first 5 months of 2000
- Both companies with many NDAs and companies with fewer NDAs

Electronic submissions - FDA perspective - Voluntary electronic NDAs

Percentage of original NDAs including electronic component

- 1998 – 30%
- 1999 – 49%
- 2000 – increase without review aids

Electronic submissions - FDA perspective - Voluntary electronic NDAs

Since November 1997

- 45% of all applications were submitted with an electronic component
- 80% of have either electronic CRFs and/or CRTs
- 15% are complete submission

Electronic submissions - FDA perspective
Reduction in submissions in paper

Reduction in the average number of paper volumes from 1997
1998 - 20% reduction
1999 - 30% reduction
2000 - 50% reduction

Electronic submissions - FDA perspective - Reviewer response - individual interview

- Most reviewers have not seen a complete electronic NDA
- Benefits most obvious with repeat submissions
- Confusion if experience with electronic submissions based on CANDAs or non guidance electronic submissions

Electronic submissions - FDA perspective - Reviewer response

Most of problems deal with difficulties with loss of individual choice for:

- **Paper or electronic**
  - **Up to applicant**
    - **Reviewer wanted electronic but was given paper**
- **File format**

Electronic submissions - FDA perspective - Reviewer response

Improvement in usefulness of electronic submissions - internal changes

- Upgrade to Acrobat 4.0 with improved copy and paste function and compare
- Increased availability to dataset analysis software
- Training
- Improved hardware (e.g., monitors)
- More experience with electronic submissions

Electronic submissions - FDA perspective - Reviewer response

Improvement in usefulness of electronic submissions - external changes

- Text vs image based PDF documents
- Well documented and organized datasets
- Sponsor also uses electronic submission

Electronic submissions - FDA perspective - Internal issues

- Lack of reviewer awareness of guidance and efforts for electronic submissions
- Continued individual requests that differ from guidance
  - Paper copies
  - Other file formats

Electronic submissions - FDA perspective - Internal issues - being addressed

- Training courses
- Manuals of policy and procedures
  - Non archival file formats
- Internal education talks
- Surveys
- Individual discussion
  - Issues many times easy to resolve

Electronic submissions - FDA perspective - Internal issues - being addressed

We can fix what we don't know

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Electronic submissions - FDA perspective - External issues

- **Lack of awareness of guidance and efforts for electronic submissions**
- **Continued individual submissions that differ from guidance**

Electronic submissions - FDA perspective - External issues

Technical problems delaying processing

- Physical media not noted in guidance
- Send archival copy to division
- Mix archival with non archival copies
- Do not use guidance folder names
- Include non archival files in archive

Electronic submissions - FDA perspective - External issues - being addressed

- Send archival copy to Central Document Room
- Send non archival copy directly to reviewer
- No review aids except:
  - Exact copy of archive files
  - Draft labeling in Word
  - Program code files in ASCII

Electronic submissions - FDA perspective - External issues - being addressed

- Workshops
- Web page
- Clarify guidance
- Manuals of policy and procedures
- Individual discussion

Electronic submissions - FDA perspective - Selling points for electronic submission

- Better quality than paper submissions
- Better organized and more complete
- Easier to process and find documents
- Improved review efficiency
- Technology used with many submissions
- Going to be required

Information and help:

CDER electronic submission web site:
www.fda.gov/cder/regulatory/ersr/default.htm

Technical help
esub@cder.fda.gov

Whatever
levinr@cder.fda.gov